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# The Politics of Pharmaceutical Regulation in Nigeria: Policy Options for Third World Countries

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**Abstract**
This paper examines the influence of politics on the regulation of the pharmaceutical industry in Nigeria by the National Agency for Food and Drug Administration and Control (NAFDAC). Noting that social regulation is inseparable from politics, the paper argues that certain characteristics of the pharmaceutical industry itself predisposes it to corruption, thus emphasizing the need for regulatory agencies to be strong and determined in carrying out their duties. Drawing insights from two case studies in pharmaceutical regulation in Nigeria, and on the basis of evidence gathered through personal interviews with stakeholders in the industry, the paper demonstrates that regulation of the pharmaceutical sector touches the cords of divergent powerful interests in business and can, therefore, be acrimonious. This is true particularly of developing or Third World economies where the bulk of pharmaceutical products are imported; and where governments often establish weak institutions, processes and structures to control pharmaceutical products manufacturing, distribution and drug prescribing in an environment where the existence of cartels built on free enterprise is the norm rather than the exception. The paper discusses the implications of these factors for social regulation in general and suggests social governance through collaborative public policy-making and implementation to make regulation less acrimonious. In the very essential pharmaceutical industry, this is expected to achieve a welfare-oriented balance between the pursuit of the objectives of sectoral growth, the profit motive of the entrepreneur and the quest to make safe, quality and affordable medicines available to the teeming populations in the Third World.
**Key Words:** Politics; Policy; Social Regulation; Implementation; Third World.

## 1. Introduction

Politics deals with the authoritative allocation of scarce values (Easton, 1965: 50), the determination of who gets what, when and how (Lasswell: 1936). It mediates between and amongst individuals and groups in their ordinary daily struggles for relevance and for control over the allocation of those resources that people desire, value and cherish. Some of these resources include political, social and economic power and more generally, control over the affairs of society. That is why Aristotle defines politics as the science of the state and its institutions. It therefore involves "those activities which revolve around the decision-making organs of the state and … the concepts of power, authority, command and control" (Rais Khan,et al, 1977:3). In this sense, we can define politics as the use of power to effect desired socio-economic and political outcomes.

French and Bell (1992:185) identified three primary conditions for the emergence of politics which include resource scarcity, social interdependence, and incompatibility of goals and, or means to goals (otherwise called social technology). However, Pfeffer (1981:69-70) opines that the degree of politics that will be employed in the determination of any issue will depend on two factors: one is the importance of the decision issue (or the resources) and the other is the distribution of power.

When the decision issue (or the resources in contention) is critical, power and politics will be employed to resolve (that is, determine or allocate) it; but when the issue appears too trivial to merit the investment of great political resources, less politics will be employed to determine its outcome. When power is diffused, political activity such as bargaining and coalition-building increases in the attempt to resolve issues (Pfeffer, (1981:69-70). Conversely, when power is centralized, the probability increases that less politics will be employed to resolve conflicts since the centralized authority makes its own decisions on the basis of its own rules and values.

Whether more or less of politics is used in the resolution of issues and conflicts in the state, the rules and values that convey key decisions are expressed in the form of law,and are enforced by specific authorities. In many

 

cases, governments establish administrative or regulatory agencies for the purpose of enunciating, implementing or enforcing such laws. They may be given various names such as Boards, Commissions, Offices, Bureaus, Authorities, Departments, Administrations, Corporations, Divisions, or Parastatals, etc. They often parade expertise or professional knowledge, but apply an assortment of constitutional, statutory, common, agency-made and judge-made laws to define and enforce administrative or regulatory standards on parties on matters of interest, especially where members of the public are affected. Today, regulatory agencies are numerous in North America (particularly the USA and Canada) and in Europe, and this trend is developing even in many market economies of the Third World, Nigeria inclusive.

Regulation is either social or economic in nature. Reagan (1987: 88) argues that while the primary rationale for economic regulation stems mostly from attempts to control the excesses of *laissez-faire* economics, particularly the negative effects of monopoly power in terms of price, entry, exit, etc., the economic rationales for many social regulation programmes are the problems of externalities that relate to market failure. Gerston, Fraleigh and Schwab (1988:31) submits that externality exists "when the actions of a producer or consumer imposes costs on society that are not accounted for in the costs of production". Economic regulation often adopts indirect methods that can easily achieve the defined objectives of regulation (for example, approval of tax holidays for a particular industry in order to encourage it; or raising import duties to discourage foreign competitors from affecting a sector negatively).

However, social regulation is arguably more popular because it touches on issues that affect the lives and welfare of citizens more directly, such as health, safety standards, the environment and human rights, etc. Social regulation mostly embraces direct methods that often sets regulatory agencies on collision courses with regulated industries, mainly because they touch on sensitive matters that may determine the welfare of citizens. Examples of this in Nigeria include the regulation of pharmaceutical products in order to protect citizens' health; regulation of the aviation industry to ensure air safety standards; regulation of the banking sector to protect the financial interests of customers; and environmental standards regulation to protect the environment, its resources and the people from indiscriminate use and abuse. For this reason, social regulation has been characterized by a higher level of adversarial tension, and consequently, politicking between business and government and has therefore generated more controversy.

Examples of social regulatory agencies in Nigeria include the Standards Organization of Nigeria (SON), National Drug Law Enforcement Agency (NDLEA), the National Environmental Safety Regulatory Authority (NESREA) and the National Agency for Food and Drug Administration and Control (NAFDAC), which regulates pharmaceuticals, the object of this paper.

## 2. Social Regulation and Politics

Social regulation has some characteristics that accentuate its political nature. In the first instance, regulation is aimed at checking the excesses and omissions of business that may lead to adverse consequences for the consumer (Reagan, 1987:90-101). Two, by reason of the above, regulation is necessarily confrontational in nature. For instance, NAFDAC's offices and laboratory equipment worth millions of naira got burnt in unexplained fire incidents in its Ikoyi office on March 7, 2004 (Nnani and Suku, 2004: 30). Later, the agency's Kaduna offices were burnt a few months later. Also, an assassination attempt was made on the person of the Director-General while NAFDAC officials were physically assaulted in August, 2008, by hostile residents of Ejule in the Eastern Senatorial District of Kogi State (Research Fieldwork, 2008).

Also, social regulation is political because it involves a lot of citizen participation through the policy process, both at the policy making and implementation stages. This naturally breeds politicking in the process. Apart from traditional methods of legislative lobbying to speed up or to halt the enactment of laws on particular matters (which is common in some developing countries), citizens, interest groups and professional associations in bigger and more developed economies have devised newer methods either to speed up or to scuttle policy implementation. Sometimes, this may involve initiation of lawsuits, staging of peaceful protests or other means of registering their individual and group interests. These events are political in nature.

Furthermore, specific mandates, deadlines, targets and technological requirements, that allows for less discretion than proponents of street-level bureaucracy would admit, are part of social regulation. However, if the mandate of the regulatory agency is confusing or unclear, as it sometimes happen where there are multiple laws or

 

mandates that introduce inertia into the work of the agency, the agency may become exposed to pressures, culminating in lack of understanding by members of the public.

In terms of organization and structure, social regulatory agencies are either headed by single heads or managed by commissions. Line agencies have single heads that are appointed by the President or leader of government business and reports to him either directly or through the office of a cabinet Minister, as NAFDAC does through the Minister (not Ministry) of Health. Allegiance to the Presidency is clear such that the lines of authority and accountability are clearly spelt out. However, as Reagan 1987: 92) shows, experiences with legal-administrative authority in social regulation may not always translate into effective political authority. For example, except during the tenure of President Shehu Musa Y'aradua, the Economic and Financial Crimes Commission (EFCC) during Nigeria's fourth republic has not enjoyed much independence in its operations. The presidency has often interfered with its functions. This subjects such regulators to political control and the assessment of its functions to subjective rather objective interpretations.

**3. Nature of the Pharmaceutical Industry**

The pharmaceutical industry enjoys public attention and patronage for the obvious reason that its products are desired by different strata of the population. The industry exhibits some characteristics out of which several other issues, including the challenges posed by drug distribution in Nigeria are addressed.

The first is that the pharmaceutical industry is partly a social welfare industry that cannot be left entirely to the operations of free market enterprise and the principles of demand and supply which drive it. Drugs and medicines (products of the industry) are life-saving, diagnostic, disease preventing and disease treatment substances that people require irrespective of where they live or their economic status. For this reason, drugs and medicines should not only be available but also affordable for the citizenry. Therefore, governments are interested in its development. As a perceptive observer argues:

> *Far from being a model of free enterprise, the pharmaceutical industry is utterly dependent on government-funded research and government-granted monopolies in the form of patents and exclusive marketing rights. The few innovative drugs usually stem from publicly-funded research done at government or university labs. Even among related mee-too drugs, the original is usually based on government-sponsored work*
>
> (Angell, 2006:68).

Thus, investors in the pharmaceutical sector of the economy spend less on research and development and make super profits than they would admit. In connection with the above, Angell (2006) submits further that:

> *Big drug companies actually spend relatively little on R&D far less than they spend on marketing and administration and even less than what they have left over in profits. In 2002, for example, the top ten American drug companies had sales of US$ 217 billion. According to their own figures, they spent 14% of sales revenues on R&D, but they spent twice as much, a whopping 31% on marketing and administration. And they had 17% left over as profits…if drug companies spend more on marketing and have more left over as profits, they can hardly claim that high prices are necessary to cover their R&D.*

Although the value of drugs consumed in the developing world is less than the figures for the first world in monetary terms (WHO, 1988: 8-9), profits accruing to pharmaceutical industries generally are so huge that the industry attracts a lot of prospective investors, both genuine and fake, a situation that makes the case for strict regulation of the industry important. Drugs constitute one of the fastest-moving goods in international trade. Therefore, distribution across international boundaries and within states is one aspect of administrative processes that adds to the cost of pharmaceuticals. If not properly regulated, distribution can lead to other negative effects in the health sector of the economy.

A second but related characteristic of the pharmaceutical industry is that it is very susceptible to fraud and corruption, especially through the distribution network. There are several reasons for this. One, there is the problem of asymmetric information due to the imperfect nature of the market (Lane, 2000:122-130). Pharmaceutical products manufacturers, medical practitioners, importers, wholesalers, retailers, prescribers (doctors) and dispensers (pharmacists) have informational advantages and professional competencies that the average patient does not have.

 

Under such circumstances, the regulated are likely to behave in ways that would maximize profits (opportunism and pursuit of self-interests) in their dealings with clients. Patients, on the other hand, often do not possess independent information that can help them make informed, rational choices. Profit maximization may be tolerable under capitalism; however, it can get worse and involve other forms of potentially life-threatening malpractices where regulation is absent or ineffective. The drug and pharmaceuticals distribution system in Nigeria is so poorly organized that it permits very high prices, fake, adulterated, substandard, expired drugs and other forms of unprofessional practices.

Human nature is the second reason why the pharmaceutical industry is susceptible to corruption. This is the fact that government regulation of the pharmaceutical industry to a large extent predisposes it to corruption and other fraudulent practices. The purposes of regulation are sometimes compromised because there is no guarantee that regulators will not use their powers to exercise discretion for personal advantages or to favour individuals and groups under the cover of Weber's bureaucracy (Bauman, 1989: 18, 28; Marshall, 2001). For Dunsire (1990:26), there are so many avenues for things to go wrong using bureaucratic ideals in policy implementation that it is amazing that things ever go right. Lipsky (1979: 208-210) in particular argues that certain conditions in the work environment of 'street level bureaucracies' (which drug regulation involves, for instance) may make it difficult for bureaucrats (regulatory officials on the street, for example) to respond favourably to contemporary demands for improved or more sympathetic service to some clients.

In the pharmaceutical sector, there are several critical decision points that are prime targets for corruption. These include manufacturing, registration, drug selection, procurement, distribution, drug prescription and dispensing (Cohen, Mrazek and Hawkins, 2007: 29-63). However, regulatory capture or corruption in any of the decision points can lead to public spending on medicines that is not rational in terms of safety, effectiveness and economy (Parish, 1973). In fact, such spending on drugs may not reflect the health priorities of a country. When regulatory functions are performed within the context of a bureaucratic agency that lacks transparency and accountability in the manner in which each function is performed, the opportunities for corruption increases. Such may result in the 'capture' of the regulatory agency or some of its staff.

Apart from lack of transparency and accountability, possibilities for agency capture and corruption in public regulation increases when regulatory staff can exercise wide discretionary powers due to weak legislation or failure to implement existing rules. Lane (2000: 122-125) argues further that, the possibility of corruption increases when regulated industries possess asymmetric information, when there is bounded rationality, excessive use of authority and hierarchy instead of voluntary exchange by the regulator over the regulated, or when the interests of the regulator and the regulated dominate the public interest. As an extension of Lane's argument, however, it is conceivable that the interests of the regulator and the regulated may coincide or converge. Such could be professional interests, such as when regulatory staff and staff of regulated industries belong to the same professional bodies such that professional interests begin to affect the implementation of policies to aggravate corruption in the sector.

A third reason for the pervasiveness of corruption and fraud in the pharmaceutical industry is that it has a very complex supply chain that involves many points and parties before the product reaches the final consumer or user. This long supply chain, coupled with weak regulations in many poor countries, poor enforcement of distribution standards and the difficulty in distinguishing genuine from original products in the supply chain render the sector prone to corruption and fraud. The incidence of corruption in the pharmaceutical sector is so pronounced in poor countries of the world that an estimated twenty-five per cent (25%) of drugs consumed in those countries is assessed to be counterfeit (fake) or substantial (inferior) (WHO, 2005).

The above-mentioned characteristics of the pharmaceutical sector of a nation's economy indicate that all hands must be on deck to ensure sanity and integrity in the sector. If not, the consequences may be serious, depending on what point of the sector is affected and the seriousness of the situation. As Cohen, Mrazek and Hawkins (2007: 33) argue:

> *While the nuts and bolts of a pharmaceutical system are similar from country to country, the vulnerable decision points may differ and may even vary within different levels within the same country. Each core decision point needs to function well so that the system as a whole offers safe, efficacious and cost-effective medicines. If only one decision point is vulnerable to corruption, the integrity of the entire system chain is at risk, which means that the population's access to essential medicines could be compromised.*

 

**4. Politics and the Regulation of the Pharmaceutical Industry in Nigeria**

The above characteristics of social regulation are, to a large extent, true of the regulation of the Nigerian pharmaceutical industry by NAFDAC. However, regulation is not just scientific and technical, it is also political. This is true because in real life situations, regulatory goals are not deduced wholeheartedly from scientific or technological principles alone, but rather, are also politically determined. While the contentious issues include the determination of the relative importance of politics vis-a-vis science and technology in the crystallization and determination of regulatory goals, we hasten to add that it is not only goals that are determined politically, but also the social technology required to accomplish them.

Striking this note about two decades ago, Michael Reagan argued that:

> *Regulatory decisions are at least as much political as they are technical, with 'political' here meaning 'concerned with allocation of values in society'. To allocate values is to make choice among values, since there is rarely total consensus on the value to be given primacy; there is almost always conflict over allocation decisions. The conflict involves competing ideas, individuals, and often organized interests claiming to represent various values.*
>
> (Reagan, 1987:2)

But social policy making and implementation is subject to greater acrimony in hotly contested matters such as regulation of the pharmaceutical sector. As such, most questions in regulation are not just instrumental in terms of how to achieve clearly stated objectives. The determination or crystallization of goals to be pursued is also subject to negotiations, tradeoffs, compromises and coalition-building due to different views, interests and criteria concerning multiple worthy objectives. This means that it is difficult to build consensus on what goals to pursue and how to pursue them. Pursuing more of one goal could often mean pursuing less of others, because resources are scarce, bringing to light, Bell's (1973:365) argument that "politics is haggling, or else it is force". And if politics is force, it is not too distant from acrimony, a fairly regular feature of public policy making that Reagan (1987: 5) describes as involving a combination of the three elements of goals, facts and values which he represented as:

P= G+F+V,

Where P= Policy, G= Goals, F= Facts and V= Values.

However, policymaking and implementation requires the three elements above as none of them alone is sufficient to determine policy. They are therefore interdependent in the making and implementation of policy. Weimer and Vining (1991:313) submits that thinking of policy implementation as a series of adoptions help to prepare implementers for the intrusion of the values and interests of those whose co-operation is needed to move the adopted policy from a general statement of intent to a specific set of desired impacts.

Writing on the political feasibility of policy proposals, Meltsner (1972: 859-867) provided a checklist of the information required to assess the political feasibility of public policies. According to him, these include questions like "who are the relevant actors?" what are their motivations and beliefs?" what are their political resources?" and "in which political arenas will the relevant decisions be made?" Some of these questions and considerations shall direct our discussion of the impacts of politics on the regulation of the pharmaceutical industry in Nigeria.

**5. Impact of Politics on the Regulation of the Pharmaceutical Industry in Nigeria: Two Case Studies**

As noted earlier, although social regulation often deals with issues of scientific and technological importance, professional considerations alone do not drive social regulation. To the extent that politics affects policy implementation in numerous ways, one can suggest that implementation is by and large a political process. This is because many regulatory policies meant for implementation are politically determined; the allocation of resources for policy implementation takes place through the political process; the choice of the social technology for implementation are often mediated by politics while the outcomes of implementation are politically interpreted. Two cases in the regulation of the Nigerian pharmaceutical industry will suffice to prove that regulation is by and large a political process. These are NAFDAC's efforts to establish Zonal Drug Distribution Centres (ZDDCs) across the federation and the agency's attempts to eradicate illegal open drug markets from Nigeria.

 

5.1 Case Number One: NAFDAC and the Establishment of ZDDCs

Soon after assuming office as NAFDAC Director-General in 2001, the Professor Dora Akunyili-led leadership initiated a grand plan to sanitize the chaotic drug distribution system in the country by eradicating the various open drug markets across the length and breadth of the country. According to the D.G.:

> *It is very clear to all healthcare professionals that a major source of substandard (pharmaceutical) products in Nigeria is the multitude of unregulated drug markets in our major cities. These markets have existed since the '60s and have grown in number and complexity over the years. They have survived the efforts of various Nigerian governments to forcefully dismantle them, which never succeeded, but rather ended up in a lot of bad blood against government. Having inherited this awesome chaotic distribution channels, resultant from the seemingly uncontrollable sale of drugs in the illegal markets, the present NAFDAC management therefore took a critical look and decided on a new approach.*
>
> (NAFDAC, 2001:2).

The new NAFDAC management concluded that previous efforts failed due to their ad-hoc nature and the non-provision of an alternative structure to replace the chaotic distribution system. The agency therefore planned for a sanitized drug distribution system that would be "sustainable", "multifarious", "multifaceted" and "multisectoral" based on "systematic, scientific and synchronized strategies" that the agency called its 3M + 3S= success approach (NAFDAC, 2001:2).

Under the scheme, a drug distribution centre was to be built in each of the six geo-political zones of the country and was to be managed by professional pharmacists in line with practices in some developed and developing countries where similar interventions bad been used to sanitize and restructure the drug distribution system. These include Sweden where the drug distribution system (the *APOTEKET AB*) is solely run by government and has succeeded in creating the greatest possible benefit at the lowest possible cost, such that Sweden now enjoys one of the lowest prices of quality drugs in the world (NAFDAC, 2001:4).

The pharmaceutical distribution system in each country is unique and may exhibit unique problems that may not be necessarily replicated in other countries (Cohen, Mrazek and Hawkins, 2007: 29-62). Therefore, while the Swedish *Apoteket* was designed mainly to address the vulnerability of the system at the retail level (its weakest link), the proposed Nigerian ZDDC was designed to address the vulnerability of the national drug distribution system at the wholesale level (NAFDAC, 2001: 4).

However, NAFDAC had to abandon the proposal due to several reasons, one of which was the high level of opposition to the policy by different categories of stakeholders, bringing to the fore, issues raised by Meltsner about the political feasibility of public policies and programmes. A policy may be scientifically, technically sound, socially desirable but not politically expedient. The issue of political expediency of public policy can be determined using the checklist provided by Meltsner. Therefore, we ask questions regarding who were the relevant actors in the ZDDC policy, their motivations and beliefs, the political resources they possessed and the political arenas where the critical decisions regarding the ZDDC were made.

5.1.1 Relevant Actors and their Motivations

Since the ZDDC project was aimed at restructuring the pharmaceutical distribution system in the country, the relevant actors in it included the major stakeholders in the drug distribution arm of the pharmaceutical sector of the economy. These are the professional pharmacists, the Pharmacy Council of Nigeria (PCN) and operators of the various open drug markets in Nigeria. Others are legislators in the National Assembly who were responsible for voting funds for the programme and were to back it up with appropriate legislation.

The various actors have various motivations and beliefs, all hinged on the preservation of individual and group economic interests. Operators of the open drug markets, for instance, believed that the aim of the ZDDC programme was to eradicate open drug markets, thereby throwing them out of business. They held this belief because they knew that they were not going to call the shots in the proposed Drug Marts, but rather, would be screened before entry, given definite rules on how to do the business in which they were hitherto bosses and placed under the control and supervision of qualified pharmacists. They also felt aggrieved that they were not involved in planning the programme from the scratch, but were only co-opted after every plan had been made (Interviews with traders in the Kano, Onitsha and Idumota drug markets, March –June, 2008).

The motivations and beliefs that dictated the reactions of pharmacists and the Pharmacy Council of Nigeria

 

(PCN) to the ZDDC programme are professional and economic. The Council resented what it described as "the unlawful and illegal moves of NAFDAC" to make pronouncements on drug prescription policy, claiming the agency had no powers to dabble into "the modus operandi of drug dispensing in pharmacies". Rejecting the rule by NAFDAC that no pharmacy should dispense ethical drugs without prescription, the body argued that, by virtue of Part II Section 5(a)-(b) of Decree No. 15 of 1993, and Section 1(1) d of Decree 91 of 1992, it is the PCN, rather than NAFDAC that has control over drug prescription policy. PCN noted the overlap in the relevant laws but insisted that NAFDAC can only assist it, but cannot hijack the statutory mandate of the PCN. The PCN therefore directed its members in Lagos "to resist the impending tyranny by refusing to grant entry to (NAFDAC) regulatory inspectors on unlawful assignment" (Oyedeji, 2005:33).

In their resistance to the ZDDC proposal, individual pharmacists and their professional body sought to protect their professional and economic interests by engaging in a media war against NAFDAC, such that the agency had to abandon the idea. According to the D.G.:

> *We called the pharmacists to a meeting in Oshodi and explained to them…and some made suggestions like the inclusion of a bank. (Later) there was an attack on …NAFDAC with headlines like "Drug Mart? Is it their business?" And the fight was so much that we had to re-invite pharmacists again. There we told them all over again of the aims of the drug mart. They seemed to agree but after each meeting the fight became greater. So, one day, my loved ones called me and said I am fighting drug barons, fighting pharmacists… later, my management had a meeting and the issue of drug mart was closed.*
>
> (Oyedeji, 2004:32).

Another reason that the PCN gave for its opposition to the ZDDC idea was the fact that NAFDAC did not make proper and sufficient consultations with it, preferring to inform the body only after making the vital decisions on the project (Group interview with PCN Executive, August 2008). However, the National Assembly was ready to support the agency first by agreeing to allocate N800 million to the ZDDC project, spread over the 2001 and 2002 national budgets (Oyedeji, 2004:32). But that was not to be since the agency had jettisoned the programme.

5.1.2 Political Resources of the Actors

The political resources that the various actors possessed were as diverse as the groups themselves. For instance, traders in the open drug markets, pharmacists and their professional body used media campaign to oppose NAFDAC's proposal. In addition, the PCN relied on its statutorily-given mandates to challenge NAFDAC's instructions before the Minister of Health, the Attorney-General and the Presidency (Oyedeji, 2005: 33). Therefore, the arenas of power where the critical decisions were made by the relevant stakeholders included the press, the executive and, to lesser extents, the legislature and the judiciary.

5.2 Case Number Two: NAFDAC and the Illegal Drug Markets

Open drug markets have existed in Nigeria not long after political independence. It is difficult to pinpoint their ages since they developed gradually, not from any conscious effort by government, but in response to the long years of neglect by successive administrations to take any positive decision or action on drug distribution in Nigeria.

However, there were no reported cases of fake drugs in Nigeria up till 1968 when the Crown Agents divested as the sole drugs distributor in Nigeria (Fajemirokun, 2004: 42). Even up till the late 1970s, the Nigerian pharmaceuticals market was sane because the United Kingdom remained the dominant supplier to the Nigerian pharmaceutical market. For instance, Adenika, (1988: 10) submits that up till 1983, the United Kingdom had 49.4% share of the Nigerian pharmaceutical imports, with Switzerland trailing a distant second with a market share of 14.7%.

The dominance of the open drug markets in pharmaceutical distribution in Nigeria can therefore be linked to the import license era of the Nigerian Second Republic between 1979 and 1983, when there was an indiscriminate issuance of import licence and supply contracts to professionals and non-professionals, the pharmaceutical sector inclusive. Nigerians quickly realized the lucrative nature of the trade in pharmaceuticals and the open drug markets developed as trade-centres for pharmaceuticals, particularly because the non-regulatory atmosphere provided by government inaction encouraged the trade. Today, there are open drug markets at Sabongeri in Kano, Ariaria in Aba, the Bridgehead Market in Onitsha and Idumota in Lagos, among others.

5.2.1 Relevant Actors and their Motivations

The main actors in the open drug markets are the businessmen and women who distribute drugs and medical

 

devices not only in Nigeria, but also in other West African countries. The main motivations of these business moguls are profit maximization and the protection of the business interests of members. In order to protect these interests, traders in the various markets have organized themselves into different trade associations such as National Association of Patent and Proprietary Medicine Dealers Association (NAPPMED), Association of Pharmaceutical Importers of Nigeria (APIN), and Lagos State Medicine Dealers Association (LSMDA), among others.

5.2.2 Political Resources of the Actors

The political resources of the actors in the open drug markets include their organization into strong market associations so as to protect and defend their individual and group interests. They are registered with government and therefore, are corporate citizens; they can sue and be sued. To this end, they always have lawyers who are ready to take up their cases when the need arises. They have leaders who are capable of maintaining relationships and contacts with important decision-makers such as elected members of the National Assembly, political appointees, and influential civil servants. Through these contacts, they can affect policy and the flow of resources by lobbying, by spending on media campaigns, through personal relationships, and so on.

It is noteworthy that on various occasions, NAFDAC had attempted to clean up the illegal markets. It closed the Ariaria Open Drug Market in Aba in 2002, the Sabongeri Open Drug Market in Kano in 2004, and the Onitsha Bridgehead Open Drug Market in 2007 (Yussuf, 2008: A6). In closing down the Onitsha Bridgehead Market in 2007, NAFDAC had to make use of three hundred and fifty (350) soldiers and over one hundred (100) policemen after series of efforts by the agency to do so had failed. This became necessary because it was discovered that:

> *the illegal drug market was run by a powerful cabal of ruthless business men and illegal task force…(that) used to collect N400,000.00k on a container load of fake drugs and therefore paved way for smooth landing and circulation of the counterfeit drugs…(and) also where more drug counterfeiters are trained in the country.*
>
> (Chikwe, 2007:7)

Because of the power of the cabal, NAFDAC officials began to apply for transfer to other places in order to avoid confrontation with the businessmen in the Bridgehead market (Chikwe,2007:7).

**6. The Fieldwork**

The fieldwork took place between May and August, 2008. The NAFDAC Zonal Director in Onitsha refused to introduce the researcher to the traders in the market during the field work in the market for security reasons. However, the researcher approached the traders without formal introduction through an Igbo interpreter, since Igbo businessmen dominate the market. The researcher also interviewed drug dealers at the Sabongeri Market in Kano through an Hausa interpreter. There was no need for interpreters at the Idumota drug maket in Lagos because most of the traders spoke the English language fluently while others spoke in *Pidgin* English. Surprisingly, the traders in the Sabongeri Market in Kano co-operated willingly with the researcher while those at Lagos and Onitsha did so after different levels of initial hesitation. The traders in the Onitsha Drug Market actually surrounded the researcher and his interpreter with fierce-looking bodyguards who frisked him and confiscated his recording equipment before they finally co-operated with him to interview them. The researcher had seven meetings with the traders in all (two in Kano; three in Onitsha; and two in Idumota, Lagos). The researcher also visited the Federal Ministry of Health, the Clerk of the National Assembly and the National Assembly Committee on Health to gather facts.

The main findings from the fieldwork were as follows:

i. The traders believed that, because they had always provided essential services to the citizenry, the government and NAFDAC should find ways of integrating them into the total healthcare system rather than dismantle their markets;

ii. That operators of these markets were ready to co-operate with the agency to achieve proper regulation of their markets. What they resented was NAFDAC's "high-handedness" (in their words) in doing so. This suggests that their was no communication between the two parties on what the agency was planning to do;

iii. In the attempt of the traders to remain relevant in the power equations, the executives of the traders' associations instituted self-monitoring mechanisms within their markets with the aim of sanitizing the systems by fishing out traders involved in malpractices, and handing them over to NAFDAC for discipline and where necessary, prosecution. During one of his visits to Onitsha, the researcher met some traders in pharmaceutical products who were arrested by their executive and handed over to NAFDAC for discipline and if necessary, prosecution while the agency's officials went on routine inspection in the market. What remained questionable,

 

however, was the effectiveness of this approach;

iv. In Kano, there appeared to be understanding between NAFDAC and the operators of the Sabongeri drug market. For instance, when the researcher reported in NAFDAC's Kano State office, the State Director willingly telephoned the Chairman and Secretary of the pharmaceutical traders' union to introduce the researcher to them;

v. However, in all the markets, the traders were opposed to NAFDAC's idea of a Drug Mart (or ZDDC) because they feared it would drive them out of business. In addition, they felt slighted and insulted that the agency did not involve them in planning for the Drug Mart. Therefore, they expressed a lack of faith and confidence in the agency's plans. They were not surprised that the proposed Drug Mart policy terminated at the planning stage.

(Fieldwork Research, May-August, 2008).

**7. Implications of Politics for the Implementation of Social Regulatory Policies**

The above cases have general implications for the implementation of social regulation policies, including the pharmaceutical industry in the Third World. Social regulation is important because it concerns matters that affect the lives, health, welfare, physical and economic safety of the citizenry. Without regulating such sectors, the health, safety and productivity of citizens would be compromised; whereas a healthy, confident and buoyant population is required for optimum national productivity. In the second instance, many social sectors of the economy where regulation is important are prone to lots of abuses and corruption by practitioners, such as manufacturers, distributors (or middlemen), contractors and service providers.

One of the reasons for this is often the basic or essential nature of such sectors and the services they provide. This makes people almost want to pay any price for such services or goods. Another is the possession of asymmetric information by key providers, as a result of which they may be tempted to behave unethically and unprofessionally, thus breeding unethical behaviours and corruption. The challenges are greater where, as in many Third World states, government had hitherto failed to establish institutions, rules and standards to govern such sectors. Where such exists, the operators may lack expertise, experience and/or the appropriate social technology to carry on regulation prudently.

Since social regulation is instituted to check existing and potential abuses in such key areas or sectors of the economy in the interest of the citizenry, it is often quite confrontational, as the above cases between NAFDAC and operators of the illegal open drug markets across Nigeria, proves. Finally, is the fact that regulation is political. Politics is involved in policy crystallization, design, allocation of resources for policy implementation, the implementation process itself and the evaluation of the process. Through it, some will gain while others will lose. The possibility exists that losers may want to fight back.

The implications of the findings for the implementation of social regulatory policies in Third World or developing economies like Nigeria, are as follows: One, the implementation of social regulatory policies in Third World or developing economies like Nigeria should take cognizance of the weakness of the state and its institutions vis-a-vis the strength of groups and cabals that are already active in each sector. In the particular area of pharmaceutical regulation, the Nigerian state had been historically dormant before the Akunyili-led administration of NAFDAC. The Federal Government had liberalized pharmaceutical distribution beginning from the Second Republic when import licenses were issued quite indiscriminately without regard to professional qualifications or competence. It was therefore not surprising that those who had operated in that market and had either escaped the hammer of various governments or formed alliances with them for over two decades would feel threatened by the new wave of regulation and will attempt to scuttle it.

Knowing that the problem of asymmetric information exists in the industry because the regulated have been in the market longer than the regulator and probably has more information than the regulator, the regulator should employ more of consultation than the use of absolute force in the implementation of regulatory policies in such areas. Therefore, the regulator should seek the unflinching support and co-operation of regulated industries. This may mean that reforms would be gradual or in phases.

As the example of internal monitoring by traders in pharmaceutical products show, if handled carefully, the regulated can even become willing vanguards for regulation once they are carried along and have reasons to believe that regulation will be in their interests on the long run.

Two, there are many overlaps in regulations setting up different regulatory agencies, commissions or boards in Nigeria that needs to be addressed for the bodies to function without duplication of efforts, waste of resources

 

and in several cases, conflicts between and amongst agencies, commissions or parastatals. Overlaps of functions occur because government wants to ensure that nothing is left unattended in its sphere of activities. If overlaps are poorly managed, it leads to friction in the public sphere with attendant negative consequences; if well managed, however, overlaps could be complimentary and healthy.

The dispute between NAFDAC and PCN over drug prescription policy was poorly managed such that it degenerated to press wars in newspapers. The consequence was the refusal of PCN to cooperate with NAFDAC over the establishment of ZDDCs, such that today, the programme has become a mirage while the uncoordinated distribution system continues to be a headache to NAFDAC and a pain in the neck for many Nigerians who are denied access to quality, affordable drugs that are the dreams of the drafters of the National Drug Policy. To forestall such incidents plus the losses they bring on stakeholders both now and in the future, it is recommended that the instruments setting up each body should be carefully reviewed with a view to removing such overlaps. This will help avoid friction, duplication and wastage of resources.

Three, it should be noted that enforcement of compliance with social regulatory policies in African countries can benefit from the social or communal ethics of Africa. While it is true that many African societies are fast becoming materialistic in orientation, it is equally the case that, at the level of the individual, many Africans still detest being recognized in their communities as dubious or fraudulent in their businesses or chosen professions. Thus, NAFDAC can stem the tide of corruption and abuse in pharmaceutical distribution in Nigeria by publishing the identities of proven corrupt dealers in drugs and other pharmaceutical products (drug fakers, distributors and sellers of spurious products) along with their family names, towns, streets or compounds in their country homes and ensuring circulation of such publications in those places. This can compliment prosecution to serve as a check on the activities of such merchants of death.

Four, the decree that established NAFDAC should be amended to make it an independent executive agency to report directly to the Executive President rather than through the Health Minister. This will remove various bureaucratic bottlenecks to effective performance by the agency. This observation is based on the researcher's findings during fieldwork that many staffers of the Federal Ministry of Health expect NAFDAC to relate indirectly with the Presidency through them, a situation that could slow down the pace of work by the agency. In connection with this, it should be noted that NAFDAC was able to achieve so much during the Obasanjo Presidency due to the Director General's rapport with the First Lady, (Late) Mrs. Stella Obasanjo, who facilitated direct access to the President for the D.G. (Fieldwork Research: Interview with NAFDAC's Deputy Director of Technical Services, Alhaji Ahmed Hashim, May 28, 2008).

An agency that is implementing social policy requires adequate funding for implementation to be successful. This is because implementation of social regulatory policies is often acrimonious, with regulated industries not willing to yield much ground to the regulator. If the regulator is under-funded such that it has to rely on the regulated for critical inputs, implementation may fail totally or the regulated enters into a bargain with the regulator in a manner reminiscent of agency capture by industry. On the other hand, if the regulator is well-funded by government, it becomes easier for it to maintain its independence and thus be more effective. Therefore, NAFDAC should be adequately funded by the Federal Government so that it can train its staff properly, motivate them sufficiently to resist corruptive tendencies by regulated industries and hire more staff to boost its regulatory coverage of the country's pharmaceutical market in such a way that the objectives of the National Drug Policy can be achieved optimally.

Finally, in light of the experiences of NAFDAC with the regulated industry as documented above, it is germaine for social regulatory agencies, particularly in the developing world, to adopt the collaborative approach in policy making and implementation, as suggested by Innes and Booher (2003) . This has the potential of reducing the acrimony and cost of social regulation, and increase the benefits where essential products and services are involved.

**8Conclusion**

This paper has examined the acrimonious and essentially political nature of social regulation in the developing world, citing two cases in pharmaceutical regulation from Nigeria. It identified a complicated web of excessive dependency on foreign sources for the supply of pharmaceutical products; unstructured pharmaceutical distribution systems and weak regulatory institutions, structures and processes aiming to control strong and buoyant cartels, as some of the reasons for the high politicization of pharmaceutical regulation in such countries. It suggests collaborative policy making among various stakeholders as a major way of strengthening regulation to achieve the desired balance between the objectives of sectoral growth and making safe, quality and affordable

 

medicines available to the teeming populations of such countries.

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